DEC 15 2011

510(k) SUMMARY

Premarket Notification: K113299

December 8, 2011

DEVICE: RoG™ Sports Medicine Suture Anchor

SPONSOR/MANUFACTURER:
RoG Sports Medicine, Inc.
16450 S. 104th Ave.
Orland Park, IL 60467

SUMBITTER/REGULATORY CONTACT:
Curtis Raymond
Orchid Design
80 Shelton Technology Ctr.
Shelton, CT 06484

FDA ESTABLISHMENT REGISTRATION NUMBER: 3009227834

TRADE NAME, COMMON NAME, CLASSIFICATION:

TRADE NAME: Modified RoG™ Suture Anchor

COMMON NAME: Suture Anchor

CLASSIFICATION: Class II (ref.: 21 CFR 888.3040); Product Code MBI

PREDICATE DEVICE(S):
K111590 – RoG™ Suture Anchor

DESCRIPTION OF SUBJECT DEVICE:
The subject device is screw-like in shape and composed exclusively of PEEK plastic. It is available in both standard ("knotted") and "knotless" configurations. It is also available in diameters of 5.5mm and 2.9mm and lengths of 10mm and 17mm. It is provided sterile and supplied with non-absorbable polyethylene suture. The anchor is supplied with reusable taps and guides of corresponding size.

INTENDED USE:
The RoG™ 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications:- Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.

- Wrist/hand indications:- Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
- Foot/ankle indications:- Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

The RoG™ 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows:

- Shoulder indications:- Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/hand indications: - Scapholunate ligament reconstruction.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The RoG™ 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications:- Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
- Foot/ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

PERFORMANCE CHARACTERISTICS:

Performance characteristics of the anchors have not changed from those described in K111590. Sutures supplied with the device meet the requirements of the U.S. Pharmacopeia for non-absorbable suture as well as all requirements of Class II Special

K113299

Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA; June 3, 2003".

SAFETY CHARACTERISTICS:

The device is composed exclusively of polyetheretherketone (PEEK). A Master File demonstrating safety of the material has been supplied by the PEEK supplier and shows compliance to the requirements of ISO 10993. Sterilization of the device is in compliance with ISO 11135. Sterilant residues are within the limits of ISO 10993-7.

CONCLUSION(S):

The subject device has the same design considerations, assembly configurations, performance characteristics and indications for use as the predicate device. The proposed modification consists solely of extending the current expiration date. Testing has shown the anchor, suture and packaging to be stable for the proposed period.

K113299

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

RoG Sports Medicine, Incorporated
% Orchid Design
Mr. Curtis Raymond
Senior Regulatory & Quality Consultant
1640 South 104th Avenue
Orland Park, Illinois 60467

DEC 15 2011

Re: K113299
Trade/Device Name: RoG™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 7, 2011
Received: November 16, 2011

Dear Mr. Raymond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, international and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113297 (1/2)

Indications for Use

510(k) Number (if known): K_____

Device Name: RoG™ Suture Anchor

The RoG™ 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
- Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

The RoG 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows:

- Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/hand indications: - Scapholunate ligament reconstruction.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The RoG 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications: - Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/Hand indications: - Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.

- Foot/Ankle indications: - Achilles tendon repair/reconstruction, hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: - Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
- Knee indications: - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113299